

State of Connecticut Office of Health Care Access Letter of Intent/Waiver Form Form 2030

2005 OCT 18 PH 12: 21

All Applicants must complete a Letter of Intent (LOI) form prior to submitting a Certificate of Need application, pursuant to Sections 19a-638 and 19a-639 of the Connecticut General Statutes and Section 19a-643-79 of OHCA's Regulations. Please submit this form to the Commissioner of the Office of Health Care Access, 410 Capitol Avenue, MS# 13HCA, P.O. Box 340308, Hartford, Connecticut 06134-0308.

SECTION I. APPLICANT INFORMATION

If there are more than two Applicants, please attach a separate sheet of paper and provide additional information in the format below.

	Applicant One	Applicant Two
Full legal name	Professional Home Care Services, Inc.	
Doing Business As		
Name of Parent Corporation	Specialty Pharma, Inc.	
Mailing Address, if Post Office Box, include a street mailing address for Certified Mail	104 Sebethe Drive Cromwell, CT 06416	
Applicant type (e.g., profit/non-profit)	Profit	
Contact person, including title or position	Lou Calamari President	
Contact person's street mailing address	104 Sebethe Drive Cromwell, CT 06416	

SECTION II. GENERAL APPLICATION INFORMATION

a. Proposal/Project Title:

Establishment of Outpatient Infusion Therapy Center

b. Type of Proposal, please check all that apply:

Change in Facility (F), Service (S) or Function (Fnc) pursuant to Section 19a-638, C.G.S.:

X New (F, S, Fnc)

Replacement

Additional (F, S, Fnc)

Expansion (F, S, Fnc)

Relocation

Service Termination

Bed Addition`

Bed Reduction

Change in Ownership/Control

Capital Expenditure/Cost, pursuant to Section 19a-639, C.G.S.:

Project expenditure/cost cost greater than \$1,000,000

Equipment Acquisition greater than \$ 400,000

New

Replacement

Major Medical

Imaging

Linear Accelerator

Change in ownership or control, pursuant to Section 19a-639 C.G.S., resulting in a capital expenditure over \$1,000,000

- c. Location of proposal (Town including street address): 400-2 Talcottville Road Vernon, CT
- d. List all the municipalities this project is intended to serve: Vernon; Manchester; and East Hartford
- e. Estimated starting date for the project:

f. Type of project: <u>25</u> (other outpatient) (Fill in the appropriate number(s) from page 7 of this form)

Number of Beds (to be completed if changes are proposed)

Type	Existing Staffed	Existing Licensed	Proposed Increase (Decrease)	Proposed Total Licensed
\$				

SECTION III. ESTIMATED CAPITAL EXPENDITURE INFORMATION

- a. Estimated Total Capital Expenditure: \$ 25,000
- b. Please provide the following breakdown as appropriate:

Construction/Renovations	\$10,000
Medical Equipment (Purchase)	\$ 5,000
Imaging Equipment (Purchase)	
Non-Medical Equipment (Purchase)	\$ 5,000
Sales Tax	photo and the second se
Delivery & Installation	\$5,000
Total Capital Expenditure	\$ 25,000
Fair Market Value of Leased Equipment	
Total Capital Cost	\$ 25,000

Major Medical and/or Imaging equipment acquisition:

Equipment Type		Number of Units	

Note: Provide a copy of the contract with the vendor for major medical/imaging equipment.

c. Type of financing or funding source (more than one can be checked):

X Applicant's Equity

Lease Financing

Conventional Loan

Charitable Contributions

CHEFA Financing

Grant

Funding

Funded Depreciation

Other (specify): _____

SECTION IV. PROJECT DESCRIPTION

Please attach a separate 8.5" X 11" sheet(s) of paper and provide no more than a 2 page description of the proposed project, highlighting all the important aspects of the proposed project. Please be sure to address the following (if applicable):

- 1. Currently what types of services are being provided? If applicable, provide a copy of each Department of Public Health license held by the Petitioner.
- 2. What types of services are being proposed and what DPH licensure categories will be sought, if applicable?
- 3. Who is the current population served and who is the target population to be served?
- 4. Identify any unmet need and how this project will fulfill that need.
- 5. Are there any similar existing service providers in the proposed geographic area?
- 6. What is the effect of this project on the health care delivery system in the State of Connecticut?
- 7. Who will be responsible for providing the service?
- 8. Who are the payers of this service?

Response to Section IV Questions Regarding Project Description:

Professional Home Care Services, Inc. ("PHCS") is a Connecticut corporation holding infusion therapy pharmacy licenses for the storage, dispensing and sale of parenteral, enteral and infusion therapies in connection with the provision of home infusion therapy services in Connecticut and has extensive experience regarding such therapies. PHCS proposes to introduce a new service in Connecticut that would offer infusion therapy at a central location for individuals that are not homebound. PHCS believes that there is a current, and a strong probability of an increasing future, demand for such services, and that it can provide these services in a more cost-effective manner than home infusion services for those who are not homebound. PHCS is in a position to establish and operate the proposed infusion therapy center in a manner that will assure that the proposed services will be effective, economic and of high quality. It is anticipated that, with the successful establishment of the proposed center, approval will be sought in the future for the establishment of similar centers in other Connecticut locations.

The propose infusion therapy center will be established at 400-2 Talcottville Road, in Vernon, Connecticut under an operating lease with the owner of the building. Initially four chairs for the delivery of infusion therapy will be installed at the center. Pharmaceuticals will be prepared at the JCAHO accredited PHCS pharmacy locations under sterile conditions by licensed pharmacists. Nursing services will be provided by nurses who are trained and experienced in providing infusion therapy services. It is not expected that all infusion therapy services will require physician supervision/presence. Infusion therapies for hydration and other common therapies may be infused without physician/APRN/physician assistant presence. However, infusion therapies involving biologicals or infusions where the possibility of an adverse reaction is high will be administered in the presence of a physician/APRN/physician assistant. The clinicians caring for the patients will have the appropriate and requisite credentials and training to provide the indicated level of supervision.

PHCS has consulted with a variety of commercial health insurers and other payers regarding the proposed new services and has met with encouragement from them to establish the proposed center. It is also anticipated that services with be provided pursuant to the Medicare and Medicaid programs.

Representatives of PHCS have consulted with representatives of the Connecticut Department of Public Health and the Office of the Attorney General regarding the licensure that would be required for the proposed services, and have been advised that the proposed center would be eligible for licensure as an outpatient clinic operated by a corporation pursuant to the provisions of Sections 19-13-D45 through 19-13-D53 of the Regulations of the Department of Public Health (Public Health Code).

Recently, new infusion therapies have been introduced for the treatment of certain chronic diseases, which for the longest time had no promising treatment options. These new therapies have been classified as "biologicals" and may represent the tip of the iceberg in terms of newly proven therapies. In addition to biologicals, there are many other therapies that are being shown to be most effective when administered intravenously (e.g., pain management, hydration, parenteral nutrition, anticoagulants to name just a few). Many of these therapies are appropriate for delivery outside the home, and, for many individuals, access and cost factors will make utilization of the proposed center preferable to the home services now provided.

PHCS believes that there are a number of physician offices in the service area identified in Section II.d that provide some infusion therapy services. Manchester and Rockville Hospital, which also provides infusion therapy services, is located in the contemplated service area. However, it is

PHCS' understanding that, for reasons that will be set forth in its application, as the demand for infusion therapy services outside the home increases, hospitals and physicians who currently deliver those services will be less inclined to provide them. This prospect underscores the importance of establishing centers like that proposed in order to assure continued access to infusion therapy services by those for whom home infusion is not appropriate.

404522 v1

If requesting a Waiver of a Certificate of Need, please complete Section V.

SECTION V. WAIVER OF CON FOR REPLACEMENT EQUIPMENT

I may be eligible for a waiver from the Certificate of Need process because of the following: (Please check all that apply)

This request is for Replacement Equipment.

The original	equipment was	authorized by	the Commissio	n/OHCA in Docket
Number: _	•	-		

The cost of the equipment is not to exceed \$2,000,000.

The cost of the replacement equipment does not exceed the original cost increased by 10% per year.

Please complete the attached affidavit for Section V only.

AFFIDAVIT

Applicant: Professional Home CAME Services Inc.	
Applicant: Professional Home Care Devuices Inc. Project Title: Establishment of Outpatient Infusion Thorapy Contr	er
(Name) (Position - CEO or CFO)	
· ·	
of <u>Professional Home Care</u> being duly sworn, depose and state that the	
nformation provided in this CON Letter of Intent/Waiver Form (2030) is true and accurate to Pro fอราชาลา เปรษาย Care	
the best of my knowledge, and that <u>(ervices, Enc.</u> complies with the appropriate and (Facility Name)	
applicable criteria as set forth in the Sections 19a-630, 19a-637, 19a-638, 19a-639, 19a-486	
and/or 4-181 of the Connecticut General Statutes.	
Signature 10/4/05 Date	
Subscribed and sworn to before me on 1014/05	
MARCIA L. BRAINERD Notary Public/Commissioner of Superior Court MARCIA L. BRAINERD NOTARY PUBLIC STATE OF CONNECTICUT My Commission Expires 10/31/2007	
My commission expires:	

Project Type Listing

Please indicate the number or numbers of types of projects that apply to your request on the line provided on the Letter of Intent Form (Section II, page 2).

Inpatient

- 1. Cardiac Services
- 2. Hospice
- 3. Maternity
- 4. Med/ Surg.
- 5. Pediatrics
- 6. Rehabilitation Services
- 7. Transplantation Programs
- 8. Trauma Centers
- 9. Behavioral Health (Psychiatric and Substance Abuse Services)
- 10. Other Inpatient

Outpatient

- 11. Ambulatory Surgery Center
- 12. Birthing Centers
- 13. Oncology Services
- 14. Outpatient Rehabilitation Services
- 15. Paramedics Services
- 16. Primary Care Clinics
- 17. Urgent Care Units
- 18. Behavioral Health (Psychiatric and Substance Amuse Services)
- 19. MRI
- 20. CT Scanner
- 21. PET Scanner
- 22. Other Imaging Services
- 23. Lithotripsy
- 24. Mobile Services
- 25. Other Outpatient
- 26. Central Services Facility

Non-Clinical

- 27. Facility Development
- 28. Non-Medical Equipment
- 29. Land and Building Acquisitions
- 30. Organizational Structure (Mergers, Acquisitions, Affiliations, and Changes in Ownership)
- 31. Renovations
- 32. Other Non-Clinical